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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/688,214	10/15/2003	Ivan Osorio	011738.00137	7258

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EXAMINER

MANUEL, GEORGE C

ART UNIT	PAPER NUMBER
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3762

MAIL DATE	DELIVERY MODE
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01/15/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/688,214

Applicant(s)

OSORIO ET AL.

Examiner

George Manuel

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11/6/07.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-14 and 16-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Badura et al '234 in view of Branton (US 3,916,923).

Badura et al fails to disclose initiating a cycle ON timer that is responsive to receiving an ON command signal.

Branton teaches a "fail safe" mechanism that is tied into a circuitry and includes a timer set for a period slightly longer than the combined washing and rinse cycles. In the event of a malfunction which results in the washing or sanitizing cycle not being completed within the normal period, the timer in the fail safe circuit will time out and open the circuit to the power lines. Also, Branton teaches incorporating a 24-hour timer in an apparatus, so the sanitizing cycle will be automatically initiated at a preset time and will be completed before a dairyman reaches the barn.

One of ordinary skill in the art would have found it obvious to use the initiating cycle ON timer that is responsive to receiving the ON command signal as taught by Branton for providing safety in addition to the redundancy means disclosed in the device of Badura et al for ion beam therapy.

The addition of a timer and its initiator do not otherwise inhibit or limit the ability of the device disclosed in Badura et al to function with redundancy means for ensuring treatment therapy is turned off.

The beam guidance is checked by using redundancy means for a redundant termination of extraction and their functionality is checked, and checking of the ability of beam guidance dipoles in the beam guidance to connect and disconnect is carried out, wherein after an unsuccessful termination request and establishment of an ion beam, a renewed termination request is requested via a separate redundant channel and for independence from a control of an acceleration device, a special cable connection to a last dipole of the beam guidance upstream from a treatment site is provided to a power supply unit, so that a connection of this dipole can be effected only from a therapy supervisory control room via a special signal, wherein a check of connections and terminals of the therapy supervisory control room to the last dipole of the beam guidance and to the redundant channel for an additional termination of extraction is carried out prior to each block of irradiation procedures.

One of ordinary skill in the art would have found it obvious to use a timer for timing the interval between the first termination request and the second redundant

request because ion beam therapy may comprise residual particle counts. Badura et al suggests that high particle counts should trigger an alarm for switching off the beam and that particle count may vary. See col. 11, lines 31-59.

Regarding claim 4, the examiner is interpreting the disclosed medical electron accelerator disclosed in Badura et al to comprise electrical stimulation treatment therapy.

Regarding claims 5, 6, 9, 12 and 19-22, Badura et al teach loading computer programs and data sets into the control computer of the ion beam therapy system and checking for accurate loading in order to be able to correctly load data required for the irradiation of a patient into the sequence control of the system. Irradiation may commence for only correctly loaded data. Special programs in the server computers allow the supervisory control system to check that programs and data are written into the individual processors of the control computer and read back and compared with the programs and data stored in the individual memories. One of ordinary skill in the art would have found it obvious to modify the computer executable instruction to further time the interval between termination requests as discussed above for the reasons set forth above because Baura et al teach the readiness for operation of all computer programs and a possible emergency shutdown or release of an irradiation procedure by the medical operating console of the therapy system may be computer controlled.

Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Strul et al '681 in view of Branton (US 3,916,923).

One of ordinary skill in the art would have found it obvious to use the initiating cycle ON timer that is responsive to receiving the ON command signal as taught by Branton for providing safety to the device disclosed in Strul et al.

Strul et al disclose software controlled limits for temperature, power, and impedance (that turn off power if exceeded), there are also redundant hardware controls, including comparators 90, 96, that turn off power if the maximum temperature or power is exceeded. One of ordinary skill in the art would have found it obvious to provide a timer for initiating the redundant hardware controls because temperature, power, and impedance have residual energy capacities that diminish with time to allow for a more accurate determination of whether they have been exceeded.

Response to Arguments

Applicant's arguments filed 11/6/07 have been fully considered but they are not persuasive.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, there is

motivation to combine the references to prevent a device from harming a patient or to prevent a device from malfunctioning.

Applicants assert that Branton is not analogous art because Branton's device is related to a washing and sanitizing system.

The examiner must determine what is "analogous prior art" for the purpose of analyzing the obviousness of the subject matter at issue.

"Under the correct analysis, any need or problem known in the field of endeavor at the time of the invention and addressed by the patent [or application at issue] can provide a reason for combining the elements in the manner claimed."

Thus a reference in a field different from that of applicant's endeavor may be reasonably pertinent if it is one which, because of the matter with which it deals, logically would have commended itself to an inventor's attention in considering his or her invention as a whole.

The teachings for which the Branton device is being relied upon are not washing and sanitizing, but rather the features of initiating a cycle ON timer.

Safety of use is a concern for all devices regardless of their art specific teachings. A device with an "automatic" operation feature is subject to creating a dangerous or catastrophic situation if the device's operation is not contained. One of ordinary skill in the art would have found it obvious to look toward the device of Branton for how the operation of the washing and sanitizing system is controlled for preventing a dangerous or catastrophic situation because the device is automatic. Likewise, one of ordinary skill in the art would have found it obvious to use the operation controlling of

Branton with the device of Badura et al because there is a potential for catastrophe if the ion beam therapy is not contained. Also, one of ordinary skill in the art would have found it obvious to use the operation controlling of Branton with the device of Strul et al because there is a potential for catastrophe if the tissue ablation therapy is not contained.

“The test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference.... Rather, the test is what the combined teachings of those references would have suggested to those of ordinary skill in the art.” In re Keller, 642 F.2d 413, 425, 208 USPQ 871, 881 (CCPA 1981). See also In re Sneed, 710 F.2d 1544, 1550, 218 USPQ 385, 389 (Fed. Cir. 1983) (“[I]t is not necessary that the inventions of the references be physically combinable to render obvious the invention under review.”); and In re Nievelt, 482 F.2d 965, 179 USPQ 224, 226 (CCPA 1973) (“Combining the teachings of references does not involve an ability to combine their specific structures.”).

Applicants may argue that the examiner’s conclusion of obviousness is based on improper hindsight reasoning. However, “[a]ny judgement on obviousness is in a sense necessarily a reconstruction based on hindsight reasoning, but so long as it takes into account only knowledge which was within the level of ordinary skill in the art at the time the claimed invention was made and does not include knowledge gleaned only from applicant’s disclosure, such a reconstruction is proper.” In re McLaughlin 443 F.2d 1392, 1395, 170 USPQ 209, 212 (CCPA 1971). Applicants may also argue that the combination of two or more references is “hindsight” because “express” motivation to

combine the references is lacking. However, there is no requirement that an "express, written motivation to combine must appear in prior art references before a finding of obviousness." See Ruiz v. A.B. Chance Co., 357 F.3d 1270, 1276, 69 USPQ2d 1686, 1690 (Fed. Cir. 2004).

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George Manuel whose telephone number is (571) 272-4952.

/George Manuel/
George Manuel
Primary Examiner
Art Unit: 3762